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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,286	01/12/2007	Julian Andreev	30694/39618A	6574
4743 7590 12/15/2008 MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606				
EXAMINER				
LI, RUXIANG				
ART UNIT		PAPER NUMBER		
1646				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/579,286

**Applicant(s)**

ANDREEV ET AL.

**Examiner**

RUIXIANG LI

**Art Unit**

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/86)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

## **REQUIREMENT FOR UNITY OF INVENTION**

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-25, drawn to method of screening for an inhibitor of an active KIT tyrosine kinase receptor in a cell, comprising contacting a cell comprising an active KIT tyrosine kinase receptor with a candidate inhibitor and detecting KIT activity by using a phosphotyrosine-specific antibody to determine the amount of KIT tyrosine phosphorylation in the presence and in the absence of said inhibitor.
  - II. Claims 26, drawn to a kit for screening an inhibitor of active KIT tyrosine kinase receptor comprising a phosphotyrosine antibody.
  - III. Claim 27, drawn to a method of treating a condition.
  - IV. Claim 28, drawn to a method for designing a treatment regimen for a patient with a mast cell disorder.
2. The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Invention Group I-IV lack unity of invention because even though the inventions of these groups require the technical feature of a KIT tyrosine kinase receptor, an inhibitor thereof, and a method of screening for an inhibitor of KIT tyrosine kinase receptor. This technical feature is not a special technical feature as it does not make a contribution over the prior art in view of Lipson et al. (U.S. Patent No. 7,211,600 B2, May 1, 2007; 102 (e) date: Dec. 22, 1999). Lipson et al. teach a KIT tyrosine kinase (column 6, the 4<sup>th</sup> paragraph) and a method of screening for an inhibitor of a KIT tyrosine kinase receptor comprising contacting a cell comprising an active KIT tyrosine kinase receptor with a candidate inhibitor and detecting KIT activity by using a phosphotyrosine-specific antibody to determine the amount of KIT tyrosine phosphorylation in the presence and in the absence of said inhibitor (column 27, see, e.g., the third paragraph). Therefore, the shared technical feature does not make a contribution over the prior art

Accordingly, Groups I-IV are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Thus, unity of invention is lacking and restriction is appropriate.

3. Furthermore, the application contains claims which are directed to three KIT tyrosine kinase receptor sequences as represented by SEQ ID NOS: 2, 4, and 6. These KIT tyrosine kinase receptors lack unity of invention in view of Lipson et al. (U.S. Patent No. 7,211,600 B2, May 1, 2007; 102 (e) date: Dec. 22, 1999). Lipson et al. teach a KIT tyrosine kinase (column 6, the 4<sup>th</sup> paragraph). Therefore, even though these sequences require the technical feature of a KIT tyrosine kinase receptor, the shared

technical feature does not make a contribution over the prior art. Accordingly, unity of invention is lacking and restriction among the sequences is appropriate.

Applicant is advised that a reply to this requirement must include an identification of an amino acid/ nucleic acid sequence that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. **The Examiner notes that this is not a species election requirement; rather it sets forth additional invention groups.**

#### ***Species Election***

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

(i). mutations in the constitutively active KIT tyrosine kinase receptor as listed in claims 3, 5, and 7.

(ii). The species of tumors are as listed in claims 25 and 27.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: claims 2 and 24.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species listed above are not regarded as being of similar nature because (i) the mutations do not share the same structural features and (ii) the tumors possess distinct pathological features.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (l).

#### ***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/  
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.  
December 9, 2008